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10/631,204	07/31/2003	James E. Selis	1142-001	2183

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/631,204

Applicant(s)

SELIS, JAMES E.

Examiner

Melanie Tyson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 5 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/10/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it contains the misspelled word "anther". Change "anther" to --another--. Correction is required. See MPEP § 608.01(b).
2. The use of the trademark MAMMOTOME and GEL MARK has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. Claim 5 is objected to because of the following informalities: The claim contains the broad terms "about" and "substantially". Although one skilled in the art would understand what is being claimed in light of the specification, these terms should be removed in order to improve the precision and clarity of what is being claimed. Appropriate correction is required.
4. Claim 15 is objected to because of the following informalities: The claim contains the broad term "substantially". Although one skilled in the art would understand what is being claimed in light of the specification, this term should be removed in order to improve the precision and clarity of what is being claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dowlatshahi (Patent No. 5,853,366).

Dowlatshahi discloses a clip (marker; Figure 1A, element 10) comprising a first portion (12) that is straight and at least one additional second portion (portion opposite first portion; also referred to as element 12) that is straight and connected to the first portion (12) at an apex (16). Figure 2A shows both portions can also be arcuate. The first and second portions (12) are adapted to permit the marker (10) to compress to fit within a tube (20) of a delivery device (100; column 10, lines 61-63) and to elastically deform from a collapsed state to its original size and shape (column 10, lines 61-64) upon exiting the tube (20) for engaging tissue (column 11, lines 32-36).

7. Claims 6 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Esposito et al. (International Publication No. WO 00/24320).

Regarding claim 6, Esposito et al. disclose a device (Figure 11, element 100) for deploying a clip (Figure 15, element 160) comprising a gripping portion (head portion; 124) having two opposing finger grips (each side of 124) attached to a hub portion (112). Figure 12 shows a tube (140) joined with the hub portion (112); the tube (140) having an end hole (not labeled; Figure 14) defined at one end portion. Figure 12 also

shows a driver (push rod; 132) having an actuator member (plunger; 116) in driving relation therewith. Esposito et al. disclose that upon translation of the actuator member (116), the driver (132) advances through the hub portion (112) and the tube (140) to advance the clip (160) located in the tube (140) toward and along a ramp (curved channel; 150) for expulsion through the respective hole (distal end hole, not labeled), wherein the device does not include a lock for preventing deployment (page 10, lines 5-9).

Regarding claim 13, Figure 16 shows the actuator (116) is inherently capable of requiring only one hand to operate, since all the user would have to do is push the actuator (116), which could be done with either the users palm or thumb of one hand, while using the fingers of the same hand to hold the device at the gripping portion (124).

Regarding claim 14, Figure 16 shows the device (100) is inherently capable of being used ambidextrously, since the user can use either hand to rotate the device and align the distal end hole (150) with the clip placement site, and the user can use either hand to hold the device and operate the actuator as described above.

Regarding claim 15, Figure 3 shows an alternative embodiment of the finger grips (two halves 13), which are semicircular.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi in view of Sirimanne et al. (Patent No. 6,371,904 B1).

Regarding claim 2, Dowlatshahi discloses a clip, or marker, as described above. Dowlatshahi also discloses the marker (Figure 1A, element 10) elastically deforms relative to the apex (see Figure 6B for illustration) from a collapsed state to its original size and shape (column 10, lines 61-64) upon exiting the tube (140). Dowlatshahi does not disclose that the marker is a wire. Like Dowlatshahi, Sirimanne et al. disclose a marker (Figures 1A-1K, element 158). Unlike Dowlatshahi, Sirimanne et al. disclose the marker (158) can be a wire or suture (column 10, line 20) so that the marker (158) can be configured in a particular pattern within the body of the deploying device (Figure 6B, element 606; column 10, lines 24-27). Sirimanne et al. also disclose the marker (158) can be made of a non-bioabsorbable radiopaque material such as stainless steel, titanium, a nickel containing metal, or a polymer (column 10, lines 54-59, and 63-66) so that it can be located by non-invasive techniques (column 10, lines 48-50). Therefore, to construct the marker of Dowlatshahi from wire made of stainless steel, titanium, a nickel containing metal, or a polymer as taught by Sirimanne et al. would have been obvious

to one of ordinary skill in the art at the time the invention was made so that the marker could be configured into a shape that is desired by the user while being detectable after deployment by non-invasive imaging techniques.

Regarding claim 3, Dowlatshahi in view of Sirimanne discloses the marker (Dowlatshahi, Figure 1A, element 10) is adapted to be deployed to a predetermined site (Dowlatshahi, column 5, lines 18-21) in the absence of an applied vacuum (only plunger 116 and push rod 132; Dowlatshahi, column 8, lines 45-50).

Regarding claim 4, Dowlatshahi in view of Sirimanne discloses the distal end (Dowlatshahi, Figure 1A, element 14) of each leg portion (12) of the marker (10) may include a barb or similar extension (Dowlatshahi, column 6, lines 34-38).

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi in view of Barsch (Patent No. 6,234,177 B1).

Dowlatshahi discloses a clip, or marker, as described above, having a largest dimension of less than about 1 cm (3 mm – 6 mm; column 6, lines 30-32) and is configured for insertion into breast tissue, since tumors and cysts are tissue mass also found in breast tissue (column 5, lines 16-19). Upon exiting the delivery device (Figure 2A, element 100), the first and second portions (12) are configured to engage the breast tissue (via a barb or similar extension) such that the marker (10) becomes substantially immobile (the barb inhibits or prevents movement; column 6, lines 34-38). Dowlatshahi also discloses the marker (10) is observable through ultrasound devices, mammography devices, or both (conventional radiographic, sonographic, thermographic, or magnetic techniques; column 5, lines 40-46). However, Dowlatshahi

does not disclose the marker is made of memory shape material. Like Dowlatshahi, Barsch discloses a marker (Figure 4A, element 42). Unlike Dowlatshahi, Barsch discloses the marker is made of memory shape material (Memory metal; column 6, lines 31-32) so that the marker is resilient (column 6, lines 26-32). Therefore, to construct the marker of Dowlatshahi out of memory shape material as taught by Barsch would have been obvious to one of ordinary skill in the art at the time the invention was made so that the marker self-biases from its compacted state to an expanded state once it exits the deployment device.

12. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esposito et al. in view of Klein et al. (International Publication No. WO 00/67833).

Regarding claim 7, Esposito et al. disclose a deployment device as described above, however, Esposito et al. does not disclose a luer lock mechanism on the hub portion. Like Esposito et al., Klein et al. disclose a deployment device (hypodermic needle; Figure 1, element 24). Unlike Esposito et al., Klein et al. disclose a luer lock mechanism (luer taper on inner wall surface 52 of hub 42) for the attachment of the tube (needle formed of hypotube; 44) to the hub portion (42) so that the deployment device (24) would be able to withstand the high pressures required to inject suspended solids through the needle (page 4, lines 8-11). Therefore, to construct the device of Esposito et al. with a luer lock mechanism on the hub as taught by Klein et al. would have been obvious to one of ordinary skill in art at the time the invention was made so that the deployment device would be able to withstand the high pressures required to deploy the marker through the end hole and into the tissue.

Regarding claim 8, Esposito et al. in view of Klein et al. disclose a needle (Esposito; guide tube, Figure 12, element 114) spaced apart and concentrically located about the tube (140), since the tube (140) is moveable within the needle (114; see Figures 13 and 14 for illustration).

13. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esposito et al. in view of Voegele et al. (Patent No. 6,220,248 B1).

Regarding claim 9, Esposito et al. disclose a device as described above, however, Esposito et al. do not disclose an indicator for providing feedback. Like Esposito et al., Voegele et al. disclose a marker (Figure 18, element 61). Unlike Esposito et al., Voegele et al. disclose an indicator for providing audible and tactile feedback, as well as an indicator window for providing physical or visual feedback so that the user has confirmation that the marker has been ejected (column 8, lines 26-29). Therefore, to construct the device of Esposito et al. with an indicator providing physical or audible feedback as taught by Voegele et al. would have been obvious to one of ordinary skill in the art at the time the invention was made so that the user knows when the marker has been ejected.

Regarding claim 11, Esposito et al. do not disclose the device is adapted for cyst aspiration. Like Esposito et al., Voegele et al. disclose a device (Figure 1, element 55) for deploying a marker (Figure 18, element 61) at a biopsy site (column 1, lines 5-6). Unlike Esposito et al., Voegele et al. disclose the device (55) is adapted to remove a breast biopsy (column 7, lines 32-34) so that the device can define and mark particular locations in the tissue during and after a biopsy procedure (column 1, lines 6-10).

Voegele et al. also disclose a biopsy includes a needle aspiration biopsy (column 1, lines 37-38), therefore, it is obvious that the device could be used for cyst aspiration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the device of Esposito et al. for aspiration purposes as taught by Voegele et al. in order to be able to place markers at the aspiration site during and after the aspiration procedure.

14. Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esposito et al. in view of Dowlatshahi et al.

Regarding claim 10, Esposito et al. disclose a device as described above, however, Esposito et al. do not disclose a visual indicator. Like Esposito et al., Dowlatshahi discloses a device (Figure 7B, element 50) for deploying a marker (10). Unlike Esposito et al., Dowlatshahi discloses an indicator (markings or indicia; Figure 5, element 39) on a tube (30) in order to indicate the position of the tube (39) relative to the guide member (20), and to prevent the tube (30) from being inserted to far (column 9, lines 56-61). Therefore, to provide an indicator on the device of Esposito et al. as taught by Dowlatshahi would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the user with a way to determine the position of the tube.

Regarding claim 16, Esposito et al. do not disclose the clip comprises two portions. Dowlatshahi discloses a clip, or marker, (Figure 1A, element 10) having a general V-shape comprising a first portion (12) that is straight and at least one additional second portion (portion opposite first portion; also referred to as element 12)

that is straight. In this manner, the marker (10) is capable of at least partially collapsing such that the leg portions (12) shift toward each other when urged through a constricted area, such as the tube (20) of the delivery device (100), and then substantially resuming its original V-shape upon discharge from the tube (20; column 5, lines 51-62); in other words the marker (10) elastically deforms from a collapsed state to its original size and shape relative to each other upon exiting the tube (20) for engaging tissue (column 11, lines 32-36). Therefore, to construct the marker in a V-shape with two portions as taught by Dowlatshahi would have been obvious to one of ordinary skill in the art at the time the invention was made so that the marker can collapse to fit into a delivery device, and then expand upon exiting the device to engage tissue.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esposito et al. in view of Barsch.

Esposito et al. disclose a device as described above, however, Esposito et al. do not disclose a notch in the hub portion. Like Esposito et al., Barsch discloses a device (Figure 4B, element 40) for deploying a marker (42). Unlike Esposito et al., Barsch discloses a notch (indentation; Figure 11, element 78) in the hub portion (68) that mates with the knob of the plunger (52) to indicate that the axially inclined surface of the plunger (70) is aligned with the aperture (Figure 6, element 22; column 7, lines 36-39). Therefore, to construct the device of Esposito et al. with a notch in the hub portion would have been obvious to one of ordinary skill in the art at the time the invention was made in order to align the components of the deployment device.

16. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voegelé et al. in view of Atalar et al. (Patent No. 6,549,800 B1).

Regarding claim 17, Voegelé et al. discloses the method of pushing an actuator (Figure 1, element 57) and driver (push rod; Figure 2, element 46) along the inside portion of the needle (44) resulting in the insertion of a clip (marker; Figure 14, element 61) into a biopsy site (column 1, lines 5-6) to mark the same (column 8, lines 23-26). Figure 14 shows the marker (61) comprises a first portion (63) that is straight, and at least one additional second portion (64) that is straight and that is connected to the first portion (63) at an apex (62). Figures 16-18 illustrate that the first and second portions are adapted to fit within a tube (not labeled) of the delivery device (not labeled) and to elastically deform from a collapsed state to its original size and shape about the apex upon exiting the tube for engaging the tissue at the intended site. The phrase "insertion of a clip into a breast cyst" is given limited weight, and the clip disclosed by Voegelé et al. is capable of being inserted into a breast cyst. However, in the alternative, it would have been obvious to one of ordinary skill to insert the clip into a breast cyst for marking purposes.

Voegelé et al. disclose a method of performing a breast biopsy, but does not disclose a method of inserting a needle into a fluid filled breast cyst and removing the fluid. Atalar discloses a method comprising the steps of inserting a needle into a fluid filled internal cyst (which includes breast cysts), and removing fluid from the cyst (column 12, lines 37-45) for diagnostic or treatment purposes (column 12, lines 42-44). The collapsing of the walls of the cyst is an obvious effect of removing its fluid, since the

fluid is what gives the fluid filled cyst its shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method as taught by Atalar in order to be able to mark an evacuated breast cyst, in turn facilitating its diagnoses and/or treatment.

Regarding claim 18, it is obvious that only one hand is required for inserting the needle and marking the breast cyst using the method of Voegele et al. in view of Atalar et al., and it is also obvious that the device could be used ambidextrously, since all the user has to do is hold the device in either hand with four fingers surrounding the gripping portion (Voegele; Figure 1, element 56) and use the thumb of the same hand to push the actuator (button 58).

17. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voegele et al. in view of Atalar et al. as applied to the claims above, and further in view of Dowlatshahi.

Voegele et al. in view of Atalar et al. disclose a method as described above, however, Voegele et al. in view of Atalar et al. do not disclose the caliber of the needle. Unlike Voegele et al. in view of Atalar et al., Dowlatshahi disclose a marker deployment device (50), wherein the needle (cannula, Figure 7A, element 20) has a caliber of 18 gauge or larger (18-20 gauge; column 8, lines 8-9), in order to be an appropriate size for marking a breast lesion (column 8, lines 1-9). Therefore, to perform the method of Voegele et al. in view of Atalar et al. with a needle having a caliber of 18 gauge or larger as taught by Dowlatshahi would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to facilitate marking a breast lesion.

18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voegele et al. in view of Atalar et al. in view of Dowlatshahi as applied to the claim above, and further in view of Barsch.

Voegele et al. in view of Atalar et al. in view of Dowlatshahi disclose a method as described above, however, Voegele et al. in view of Atalar et al. in view of Dowlatshahi do not disclose a side hole on the needle. Unlike Voegele et al. in view of Atalar et al. in view of Dowlatshahi, Barsch discloses a side hole (aperture; Figure 6, element 22) on an aspiration needle (60) through which a clip (42) can be deployed so that the aperture can be closed when the plunger is rotated, in turn preventing the marker from snagging on the mouth of the aperture (22) when the needle is withdrawn from the site (column 6, lines 66-67 and column 7, lines 1-9). It is obvious that the side hole (22) could also be used for aspirating a cyst since it is in an aspiration needle. Therefore, it would have been obvious to one of ordinary skill in the art the time was made to provide a side hole on the device of Voegele et al. in view of Atalar et al. in view of Dowlatshahi as taught by Barsch in order to facilitate the deployment of the clip.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
June 15, 2006



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6/26/06